

IN THE CLAIMS:

Please amend the claims as follows:

1. (Currently Amended) Polysaccharide double-layer microcapsules constituted by an outer layer of chitosan and an inner layer of alginate ~~characterized in that~~ wherein they are obtained:

- from solutions of alginate with initial concentrations ranging from 2 to 4% w/v;
- from solutions of chitosan with initial concentrations ranging from 0.1 to 0.5 % w/v;
- from solutions of divalent ions with concentrations of 0.5% w/v, when the divalent ion functions as a gelification agent of the alginate to form single-layer capsules of alginate encapsulating at least one biologically active substance, and ranging from 10 to 15% w/v when the divalent ion has a stabilizing function of the double layer capsules for use as carriers for the oral administration of said biologically active substances.

2. (Original) Polysaccharide double-layer microcapsules as claimed in claim 1, wherein a further polymer, hydroxypropylmethylcellulose, at the initial concentration of 0.4% w/v, is dispersed in the initial solutions of alginate.

3. (Original) Polysaccharide double-layer microcapsules as claimed in claim 1, wherein the initial concentration of alginate is 4% w/v, the initial concentration of chitosan is 0.1% w/v and the divalent ion with stabilizing function on the double layer microcapsules has an initial concentration of 15% w/v.

4. (Original) Polysaccharide double-layer microcapsules as claimed in claim 1, wherein the divalent ion is calcium.

5. (Original) Polysaccharide double-layer microcapsules as claimed in claim 1, wherein the biologically active substances are selected from immunomodulants, antigens, chemotherapeutics, cytokines and growth factors.

- 6. (Cancelled)
- 7. (Cancelled)
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24. (Cancelled)
25. (Cancelled)

26. (New) Polysaccharide double-layer microcapsules as claimed in claim 1, wherein the biologically active substance is lysozyme.

27. (New) Polysaccharide double-layer microcapsules as claimed in claim 1, wherein an adjuvant is associated with the biologically active substance to increase the biological response.

28. (New) Polysaccharide double-layer microcapsules as claimed in claim 27, wherein the adjuvant is lysozyme.

29. (New) Polysaccharide double-layer microcapsules constituted by an outer layer of chitosan and an inner layer of alginate wherein they are obtained through:

- a) formation of single-layer capsules encapsulating at least one biologically active substance starting from solutions of alginate in concentrations ranging from 2 to 4% w/v, in which said substance is dispersed, by gelification with a solution of a divalent ion at a

concentration of 0.5% w/v;

b) formation of the second layer of chitosan and stabilization of the double-layer microcapsule obtained by adding a solution of chitosan in concentrations ranging from 0.1 to 0.5% w/v and containing a divalent ion in concentrations ranging from 10 to 15% w/v in the solution containing the single-layer capsules of alginate encapsulating said substance obtained in a). for use as carriers for the oral administration of said biologically active substances.

30. (New) Polysaccharide double-layer microcapsules as claimed in claim 29, wherein a further polymer, hydroxypropylmethylcellulose, at the initial concentration of 0.4% w/v, is dispersed in the initial solutions of alginate.

31. (New) Polysaccharide double-layer microcapsules as claimed in claim 29, wherein the initial concentration of alginate is 4% w/v, the initial concentration of chitosan is 0.1% w/v and the divalent ion with stabilizing function on the double layer microcapsules has an initial concentration of 15% w/v.

32. (New) Polysaccharide double-layer microcapsules as claimed in claim 29, wherein the divalent ion is calcium.

33. (New) Polysaccharide double-layer microcapsules as claimed in claim 29, wherein the biologically active substances are chosen from immunomodulants, antigens, chemotherapeutics, cytokines and growth factors.

34. (New) Polysaccharide double-layer microcapsules as claimed in claim 29, wherein the biologically active substance is lysozyme.

35. (New) Polysaccharide double-layer microcapsules as claimed in claim 29, wherein an adjuvant is associated with the biologically active substance to increase the biological response.

36. (New) Polysaccharide double-layer microcapsules as claimed in claim 35, wherein the adjuvant is lysozyme.

37. (New) A method for vaccinogenic or therapeutic treatment for the prophylaxis and therapy of infectious or non-infectious diseases by administering to a mammal, human or not human,

in need a pharmaceutical composition comprising polysaccharide double-layer microcapsules constituted by an outer layer of chitosan and an inner layer of alginate obtained:

- from solutions of alginate with initial concentrations ranging from 2 to 4% w/v;
- from solutions of chitosan with initial concentrations ranging from 0.1 to 0.5 % w/v;
- from solutions of divalent ions with concentrations of 0.5% w/v, when the divalent ion functions as a gelification agent of the alginate to form single-layer capsules of alginate encapsulating at least one biologically active substance, and ranging from 10 to 15% w/v when the divalent ion has a stabilizing function of the double layer capsules.

38. (New) The method as claimed in claim 37, wherein a further polymer, hydroxypropylmethylcellulose, at the initial concentration of 0.4% w/v, is dispersed in the initial solutions of alginate.

39. (New) The method as claimed in claim 37, wherein the initial concentration of alginate is 4% w/v, the initial concentration of chitosan is 0.1% w/v and the divalent ion with stabilizing function on the double layer microcapsules has an initial concentration of 15% w/v.

40. (New) The method as claimed in claim 37, wherein the divalent ion is calcium.

41. (New) The method as claimed in claim 37, wherein the biologically active substances are chosen from immunomodulants, antigens, chemotherapeutics, cytokines and growth factors.

42. (New) The method as claimed in claim 37, wherein the biologically active substance is lysozyme.

43. (New) The method as claimed in claim 37, wherein an adjuvant is associated with the biologically active substance to increase the biological response.

44. (New) The method as claimed in claim 43, wherein the adjuvant is lysozyme.

45. (New) The method as claimed in claim 37, wherein the prophylaxis and therapy of infectious or non-infectious diseases is applied in the animal breeding or fish farming field.

46. (New) The method as claimed in claim 37, wherein the composition of polysaccharide double-layer microcapsules are in formulations suitable for oral administration

selected from solid forms consisting of powders, tablets, capsules, or liquid forms consisting of oily or aqueous solutions, both for multiple dosage and in single doses with excipients or diluents acceptable from the pharmaceutical and feeding purposes in the human and veterinary field.

47. (New) Process for preparation of polysaccharide double-layer microcapsules constituted by an outer layer of chitosan and an inner layer of alginate comprising the following phases:

a) formation of single-layer capsules encapsulating at least one biologically active substance starting from solutions of alginate in concentrations ranging from 2 to 4% w/v, in which said substance is dispersed, by gelification with a solution of a divalent ion at a concentration of 0.5% w/v;

b) formation of the second layer of chitosan and stabilization of the double-layer microcapsule obtained by adding a solution of chitosan in concentrations ranging from 0.1 to 0.5% w/v and containing a divalent ion in concentrations ranging from 10 to 15% w/v in the solution containing the single-layer capsules of alginate encapsulating at least one biologically active substance obtained in a).

48. (New) Process for preparation of polysaccharide double-layer microcapsules as claimed in claim 47, wherein added to phases a) and b) is the phase c) of dehydration, isolation and drying of the microcapsules obtained.

49. (New) Process for preparation of polysaccharide double-layer microcapsules as claimed in claim 47, wherein a further polymer, hydroxypropylmethylcellulose, at the initial concentration of 0.4% w/v, is dispersed in the initial solutions of alginate.

50. (New) Process for preparation of polysaccharide double-layer microcapsules as claimed in claim 47, wherein the initial concentration of alginate is 4% w/v, the initial concentration of chitosan is 0.1% w/v and the divalent ion with stabilizing function on the double layer microcapsules has an initial concentration of 15% w/v.

51. (New) Process for preparation of polysaccharide double-layer microcapsules as claimed in claim 47, wherein the divalent ion is calcium.

52. (New) Process for the preparation of microcapsules as claimed in claim 47, wherein the biologically active substances are chosen from immunomodulants, antigens, chemotherapeutics, cytokines and growth factors.

53. (New) Process for the preparation of microcapsules as claimed in claim 47, wherein the biologically active substance is lysozyme.

54. (New) Process for preparation of polysaccharide double-layer microcapsules as claimed in claim 47, wherein an adjuvant is associated with the biologically active substance to increase the biological response.

55. (New) Process for preparation of polysaccharide double-layer microcapsules as claimed in claim 54, wherein the adjuvant is lysozyme.